UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OHIO EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

This document relates to:

The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al. Case No. 1:18-op-45090 (N.D. Ohio)

The County of Cuyahoga, Ohio, et al. v. Purdue Pharma L.P., et al. Case No. 1:17-op-45004 (N.D. Ohio)

MDL No. 2804 Case No. 17-md-2804 Judge Dan Aaron Polster

MEMORANDUM OF LAW IN SUPPORT OF PHARMACY DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON CAUSATION

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INTRODUCTION

Aside from the meritless allegation of a conspiracy with the manufacturers—which is addressed separately and which is unsupported by any evidence—Plaintiffs' claims against Pharmacy Defendants¹ rest on a single factual premise: that Pharmacy Defendants breached their duties related to distributing opioids by failing to detect suspicious orders. To be clear, Pharmacy Defendants deny that they breached any duty, but even if Plaintiffs could prove breach, their claims would still fail. Each cause of action requires Plaintiffs to show causation, *i.e.*, that the failure by a defendant to detect suspicious orders caused economic harm to Plaintiffs that would not otherwise have occurred.

Plaintiffs lack sufficient evidence of causation for a jury to return a verdict in their favor.

Plaintiffs cannot, as they have attempted, prove causation in the aggregate. Their proof must be addressed to each defendant individually.

To show causation from a Pharmacy Defendant's alleged failure to prevent diversion through identifying suspicious orders, Plaintiffs must provide evidence for each step in a lengthy causal chain between the alleged failure and their claimed injuries. This motion focuses on three of those steps. First, Plaintiffs must show that orders flagged as potentially suspicious would have ultimately been determined to be suspicious after investigation. Second, Plaintiffs must show that shipping such "suspicious" orders resulted in diversion (because, for example, the order was shipped to a pill mill). And third, Plaintiffs must show that the resulting diversion of the Pharmacy Defendant's suspicious orders injured them.

¹ "Pharmacy Defendants" are CVS Rx Services, Inc. and CVS Indiana, L.L.C. ("CVS Distributors"), Rite Aid of Maryland, Inc., d/b/a Mid-Atlantic Customer Support Center ("Rite Aid"), Walgreen Co. and Walgreen Eastern Co. ("Walgreens"), HBC Service Company, an unincorporated operating division of Giant Eagle, Inc. ("Giant Eagle"), Discount Drug Mart ("DDM"), and Walmart Inc. ("Walmart").

Plaintiffs make no serious effort to satisfy this causal burden. Because Plaintiffs have no evidence they have been injured by diversion from suspicious orders shipped by Pharmacy Defendants, summary judgment is warranted.

LEGAL STANDARD

Summary judgment is appropriate when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A genuine dispute of material fact exists if "there is sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Summary judgment is warranted when the non-moving party "fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

ARGUMENT

I. Plaintiffs' Claims Require Evidence of Causation.

Plaintiffs' claims against Pharmacy Defendants require proof of causation. "Proof of a causal relationship between a defendant's action and a plaintiff's injury is essential in every tort[.]" *Cleveland v. JP Morgan Chase Bank, N.A.*, No. 98656, 2013 WL 1183332, at *4 (Ohio App. Mar. 21, 2013).

Negligence requires proof of "proximate cause." *Shoemaker v. Gindlesberger*, 887 N.E.2d 1167, 1169–70 (Ohio 2008).

Plaintiffs' unjust enrichment theory is that Plaintiffs conferred a benefit upon Pharmacy Defendants "by paying for Defendants' externalities: the cost of the harms caused by Defendants' improper distribution practices." Doc. 1203 at 37-38 (quoting Second Amended Complaint at 328). Even if this were a viable legal theory (and it is not), it necessarily requires evidence that a Pharmacy Defendant's distribution practices caused harm.

Similarly, the statute allowing recovery for injuries through criminal acts—R.C. 2307.60—requires a showing that damages resulted from the crime. *Shaw v. Marion Laborers Local* 574, No. 9–13–31, 2014 WL 4198248 at *11-12 (Ohio App. 2014).

Claims for a public nuisance also require proof of proximate causation. *See City of Cincinnati v. Deutsche Bank Nat'l Tr. Co.*, 863 F.3d 474, 482 (6th Cir. 2017) ("The parties agree that to plead an absolute public nuisance claim adequately, the City's complaint must also allege facts that, if established, would show that Wells Fargo's management of its foreclosed properties proximately caused the City's asserted injuries."); *City of Cleveland v. Ameriquest Mort. Sec.*, *Inc.*, 615 F.3d 496, 502 (6th Cir. 2010).

And conspiracy requires proof of an underlying tort, *Williams v. Aetna Fin. Co.*, 700 N.E.2d 859, 868 (Ohio 1998), which necessarily requires proximate causation.

Thus, to recover against any Pharmacy Defendant under any cause of action, Plaintiffs must prove that the acts or omissions of the defendant proximately caused their injuries.

II. Plaintiffs Cannot Prove Causation in the Aggregate.

Plaintiffs must prove causation for each defendant individually. Plaintiffs cannot—as they have attempted to do—simply prove that their injuries are somehow traceable to the aggregated conduct of defendants as a whole (or even to a group of defendants). Under Ohio law, to recover against an individual defendant, Plaintiffs must prove that specific injuries were caused by the specific defendant. In *Sutowski v. Eli Lilly & Co.*, the Ohio Supreme Court considered and rejected aggregate causation (in the form of market-share liability) as incompatible with Ohio common law. 696 N.E.2d 187, 190 (Ohio 1998) ("Ohio common law has long required a plaintiff to prove that a *particular defendant* caused his or her injury through negligence." (emphasis added)). Under Ohio tort law, the Court explained, "[t]he plaintiff must establish a causal connection between the defendant's actions and the plaintiff's injuries, which

necessitates identification of the particular tortfeasor." *Id.* The Ohio Supreme Court refused to embrace a theory of proof in which "the plaintiff is discharged from proving this important causal link." *Id.*²

Under the claims asserted in this case, to satisfy their causation burden, Plaintiffs must submit evidence sufficient for an individual finding of proximate causation against each individual defendant.

III. Plaintiffs Lack Any Evidence that Pharmacy Defendants' Failure to Detect Suspicious Orders Proximately Caused Their Injuries.

It is axiomatic that "any model supporting a plaintiff's damages case must be consistent with its liability case." *Comcast Corp. v. Behrend*, 569 U.S. 27, 35 (2013) (internal quotation marks omitted). Plaintiffs' various claims rest on a single theory of liability: that Pharmacy Defendants failed to detect suspicious orders from their own retail pharmacies, an alleged breach of the duty to maintain effective controls against diversion. Pharmacy Defendants deny that any breach occurred, but even if Plaintiffs could establish breach, they lack any evidence that any failure by any Pharmacy Defendant to detect suspicious orders proximately caused their injuries.

To prove that any injuries were caused by a failure to detect suspicious orders that were diverted, Plaintiffs must provide evidence supporting each step in a lengthy chain of causation for each Pharmacy Defendant. This motion focuses on three of these steps: First, that any orders flagged as potentially suspicious by Plaintiffs' experts would have ultimately been determined to be suspicious after investigation. Second, that the shipment of any suspicious order by any

² Even when (unlike in this case) the actions of multiple defendants have contributed to a single indivisible injury, establishing liability still requires plaintiffs to prove proximate causation "as to each defendant." *Banas v. Shively*, 969 N.E.2d 274, 280 (Ohio App. 2011); *see also Pang v. Minch*, 559 N.E.2d 1313, 1324 (Ohio 1990) ("[W]here a plaintiff suffers a single injury as a result of the tortious conduct of multiple defendants, the burden of proof is upon the plaintiff to demonstrate that the conduct of each defendant was a substantial factor in producing the harm.").

Pharmacy Defendant resulted in diversion. And third, that any such diversion caused Plaintiffs injury. Plaintiffs cannot satisfy this burden.³

A. Plaintiffs fail to provide evidence that any order was actually suspicious.

First, Plaintiffs provide no evidence that Pharmacy Defendants failed to identify suspicious orders. Plaintiffs offer expert testimony from Craig McCann, whose report includes five methodologies that purportedly could be used by a distributor to flag orders for further investigation.⁴ McCann Rep., Ex. A ¶131, 136, 140, 144, 148. Notably, at his deposition, McCann expressly disclaimed that any flagged order in his report represented a "suspicious order." McCann Dep., Ex. B, Vol 1, 149:3-150:9 ("That's way beyond my report . . . I don't have an opinion one way or the other.").

Even if there were evidence that some of these orders should have been flagged as potentially suspicious, Plaintiffs present no evidence that after investigation, any order would have been determined to truly be suspicious. Even if an order initially appeared to be "suspicious" (based on the crude metrics suggested by Plaintiffs that have no basis in the CSA), it might not prove to be after investigation.

Plaintiffs' experts acknowledge that orders flagged as potentially suspicious were not necessarily actually suspicious. James Rafalski, one of Plaintiffs' experts, testified that if an order "triggers as [sic] unusual order based on the size," determining whether the order was truly

³ These are not the only flaws in Plaintiffs' causation evidence. Assuming Plaintiffs are wrong that Pharmacy Defendants had an obligation not to ship suspicious order, Plaintiffs further lack any evidence that a violation of any duty to monitor suspicious orders and report them to DEA would have prevented opioids from shipping.

Pharmacy Defendants also adopt the arguments raised in Distributor Defendants' motion for summary judgment on proximate causation, including the remoteness of Plaintiffs' alleged injuries from the conduct of shipping opioids.

⁴ Pharmacy Defendants adopt by reference the arguments in the McCann *Daubert* motion as to why McCann's opinions should be excluded.

suspicious would require "gather[ing] some facts, and ... mak[ing] an evaluation of those facts." Rafalski Dep., Ex. C, 61:17-62:10; *see also* Rafalski Dep., Ex. C, 62:1-3 (noting that possibility of "dispel[ling] the fact that it's a suspicious order); Rannazzisi Dep., Ex. D, 261:23-25 (acknowledging that an order of apparently large size "could perhaps be explained by nonsuspicious reasons").

But Plaintiffs' evidence (including McCann's report) elides this "investigation" step entirely. Plaintiffs simply assume that any unusual order should not have shipped and assume that no investigation occurred, without ever attempting to prove what an investigation would have determined. Even if the orders flagged by McCann were potentially suspicious, without evidence of what a reasonable investigation would have concluded, Plaintiffs cannot show that a flagged order was actually suspicious order and thus cannot prove causation.

Without evidence of what would have occurred if Pharmacy Defendants had investigated and attempted to dispel the suspicion for any particular order that was flagged by McCann's methodologies, Plaintiffs lack evidence of causation because they have not shown that a flagged order was actually a suspicious order.

Plaintiffs' claims thus fail for the same reason as those in *Burnworth v. Harper*, 672 N.E.2d 241 (Ohio App. 1996), which involved allegations that a tenant died of carbon monoxide poisoning because the landlord failed to inspect a ventilation system and discover a clogged flue. *Id.* at 242-43. The court of appeals held that establishing proximate cause would require not only showing the breach of duty based on the failure to inspect but also required proof that an inspection would have uncovered the clogged flue:

Even if we were to hold that the duty to maintain carries with it a concomitant duty to inspect absent notice, appellant offered no evidence showing that if appellees would have inspected the heaters or ventilation, they would have detected the presence of carbon monoxide or noticed the clogged flue. There is no evidence of when the flue became clogged or that appellees could have prevented the defect. Accordingly, without establishing proximate cause, appellant cannot prevail[.]

Id. at 245. Similarly, here, even if Plaintiffs could establish that any Pharmacy Defendant failed to investigate any potentially suspicious order, Plaintiffs cannot show that an investigation would have revealed that the order truly was suspicious.

Because there is no evidence that, after investigation, any flagged orders would have been determined to be suspicious, there can be no evidence that the failure to identify suspicious orders caused any harm to Plaintiffs.

B. Plaintiffs fail to provide evidence showing that any alleged suspicious order was diverted.

Even if there were evidence that any Pharmacy Defendant shipped suspicious orders, Plaintiffs lack evidence that any shipment of a suspicious order resulted in diversion. Plaintiffs allege that Pharmacy Defendants have breached a duty that arises from the Controlled Substances Act's requirement that distributors maintain "effective control[s] against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. § 823(b)(1). The regulatory requirement that distributors "design and operate a system to disclose to the registrant suspicious orders" and to report those orders to DEA, 21 CFR § 1301.74(b), is part of these controls. The duty that Plaintiffs seek to enforce against Pharmacy Defendants is a duty to prevent diversion.

Thus, to show that any failure by any Pharmacy Defendant to identify suspicious orders proximately caused their injuries, Plaintiffs must show that the suspicious orders were diverted. Proximate cause turns on the foreseeability of the injury as a result of the breach. *Oiler v. Willke*, 642 N.E.2d 667, 671 (Ohio App. 1994); *see also id.* at 672 ("[T]he question of foreseeability determinations is but a manner of addressing the limits of an actor's legal

responsibility, regardless of whether the analysis is conducted under the element of duty or proximate cause[.]"). In other words, proximate causation can be framed as whether "the defendant is or is not under a 'duty' to protect the plaintiff against such consequences." *Id.* at 671–72.

Even assuming that Pharmacy Defendants owed a duty to Plaintiffs to prevent diversion (which Pharmacy Defendants deny), the foreseeable harm from breaching such a duty is diversion. Thus, to recover for an alleged breach of this duty, Plaintiffs must trace their injuries to diversion that occurred as a result of suspicious orders that were shipped only because of deficiencies in a Pharmacy Defendant's suspicious order monitoring program.

But Plaintiffs lack evidence that *any* diversion occurred as a result of any alleged failure by Pharmacy Defendants to identify suspicious orders. Suspicious order monitoring is "all based on the risk of diversion." Rafalski Dep., Ex. C, 600:8-16. The failure to monitor suspicious orders "doesn't mean that diversion is going to occur." Rafalski Dep., Ex. C, 600:8-16. That is, "[n]ot every suspicious order leads to diversion." Prevoznik Dep., Ex. E, 309:4-6; *see also* Prevoznik Dep., Ex. E, 282:5-12 (testifying that skyrocketing volume "might be enough to make it a suspicious order" but not "enough to conclude its diverted"); K. Wright Dep., Ex. F, 212:24-213:2 (agreeing that "being reported as suspicious does not imply necessarily that [an order] will be diverted"). Rafalski confirmed that he "did not do any analysis to see whether any specific suspicious order caused the diversion of any specific pills for nonmedical use." Rafalski Dep., Ex. C, 469:7-16; ** see also id.* at 508:1-12 (confirming that he has no opinion about whether any

⁵ At his deposition, Rafalski made a stray comment suggesting that *all pills* were diverted from *every order* that McCann flagged as potentially suspicious. Rafalski Dep., Ex. C, 474:2-25. This comment is addressed in a *Daubert* motion challenging Rafalski's testimony, which is incorporated here. In any event, given Rafalski's repeated and unequivocal testimony that he

particular order was diverted to an illegal channel). Nor did any of Plaintiffs' other experts perform this analysis. *See, e.g.*, McCann Dep., Ex. B, 312:17-20 ("Q. Were any of what you called -- call excessive shipments diverted? A. I don't know."); McCann Dep., Ex B, 340:22-341:4 ("Q. And you have not identified any specific instances of diversion based on your review of any of the materials that you've looked at in this lawsuit, correct? A. Correct. I haven't made any attempt to do that.").

Pharmacy Defendants—uniquely among the distributors—distributed opioids only to their own retail pharmacies, where those pills were used to fill lawful prescriptions. There is no evidence that any Pharmacy Defendant distributed to an internet pharmacy or to a "pill mill," where opioids were diverted from the licit to illicit marketplace. Indeed, there is no evidence of any harm to Plaintiffs from any specific prescription filled at a retail pharmacy. *See* Doc. 1058 at 3 (Bellwether Plaintiffs' Submission in Response to Discovery Ruling No. 5: "Plaintiffs do not intend to assert, either in expert opinions or factual presentations at trial, that any specific prescription was unauthorized, medically unnecessary, ineffective, or harmful, or that the filling of any specific prescription caused or led to harm for which Plaintiffs seek to recover.").

could not identify a single diverted order, no jury could credit his testimony that every order was diverted. And such an opinion would contradict the evidence. For example, Plaintiffs identify as

This order could not have been diverted because the transactional data produced by McKesson in discovery shows that the pharmacy returned the order to McKesson in March 2012. This example conclusively refutes any opinion that every pill of every flagged order was diverted. *See Greenwell v. Boatwright*, 184 F.3d 492, 497 (6th Cir. 1999) ("Expert testimony . . . is inadmissible when the facts upon which the expert bases his testimony contradict the evidence.").

Because there is no evidence of diversion of opioids from suspicious orders that Pharmacy Defendants allegedly failed to identify, Plaintiffs lack the necessary evidence of causation.

C. Plaintiffs fail to provide evidence that they suffered injuries because of any diversion of Pharmacy Defendants' opioids.

Finally, even if Plaintiffs had evidence that opioids were diverted from a suspicious order shipped by a Pharmacy Defendant, Plaintiffs lack evidence that they suffered injuries as a result of this diversion.

Such a failure of proof is unsurprising. Because Pharmacy Defendants distributed only to their own retail pharmacies, which used these pills to fill lawful prescriptions, there is no evidence that if Pharmacy Defendants had refused to distribute opioids to their retail pharmacies, then consumers would been unable to fill their prescriptions elsewhere.

Rather than linking their injuries to diversion of suspicious orders, Plaintiffs trace their injuries to the distribution of opioids as a whole. They calculate damages based on a per-MME basis, without any consideration of whether the opioids were distributed through a "suspicious order" or through a non-suspicious order and without regard to any diversion. Professor Cutler, for example, attempts to measure Plaintiffs' damages by measuring the "percentage of costs attributable to prescription opioid shipments." Cutler Rep. at 6, Ex. H; see also id. (explaining that he analyzes "the direct effect of prescription opioid shipments on crime"). To attempt to determine the share of these costs for which distributors are responsible, Professor Cutler then uses "the share of prescription opioids that should have been identified as suspicious by distributors." Cutler Rep. at 4-5, Ex. H. But this analysis assumes that "opioid shipments" imposed equal harm on Plaintiffs (on a per-MME basis) without considering whether those shipments were suspicious or whether any diversion actually occurred. Such an analysis

bizarrely implies that "suspicious orders" posed no greater risk—and inflicted no more injury—to Plaintiffs than other legitimate orders of opioids. If that were true, Plaintiffs could not possibly trace their injuries to any allegedly tortious conduct by a Pharmacy Defendant.

Because Plaintiffs have no evidence that they have suffered any injury as a result of diversion of opioids from any suspicious order shipped by Pharmacy Defendants, they have no evidence of causation and summary judgment must be granted.

IV. Even if Plaintiffs could rely on "substantial factor" causation, Plaintiffs fail to provide evidence that diversion from suspicious shipments by any Pharmacy Defendant was a substantial factor in an indivisible injury.

Plaintiffs must prove causation of specific injuries from the specific tortious acts of each defendant, but even if Plaintiffs could show that defendants have contributed to a single, indivisible injury of "the opioid crisis," Plaintiffs would still need to prove that the conduct of each defendant was a "substantial factor" in producing the harm. See Queen City Terminals, 653 N.E.2d at 669 ("Where a plaintiff suffers a single injury as a result of the tortious acts of multiple defendants, the burden of proof is upon the plaintiff to demonstrate that the conduct of each defendant was a substantial factor in producing the harm."); Pang, 559 N.E.2d at 1324. Substantial factor causation requires more than mere evidence that a defendant may have contributed in some small way to the injury. See Schwartz v. Honeywell International, 102 N.E.3d 477, 481 (Ohio 2018) (holding that substantial factor causation was not established by evidence that "every defendant... contributed").

Given the small percentages of opioids distributed by each of the Pharmacy Defendants within the limitations period (if any were distributed at all), Plaintiffs cannot meet their burden to prove that diversion from suspicious orders distributed by any of the Pharmacy Defendants was a substantial factor in their injuries. Indeed, given the numerous potential causes of Plaintiffs' alleged injuries that turn on varying and lengthy causal chains, substantial factor causation

requires expert testimony. *Ramage v. Cent. Ohio Emergency Serv., Inc.*, 592 N.E.2d 828, 833 (Ohio 1992) ("Unless a matter is within the comprehension of a layperson, expert testimony is necessary."). But no expert testifies that diversion from suspicious orders shipped by any Pharmacy Defendant was a substantial factor in the opioid crisis as a whole. Plaintiffs thus have no evidence that any diversion from any shipments by any Pharmacy Defendant was a substantial factor in the opioid crisis in Cuyahoga or Summit County.

CONCLUSION

Under this Court's ruling denying the motion to dismiss, Plaintiffs were permitted to pursue their claims against Pharmacy Defendants for failing to identify suspicious orders. But at this stage of the case, Plaintiffs must now support those claims with evidence. *See* Dkt. No. 1203 at 39 ("Whether Plaintiffs can prove any of these allegations remains to be seen."). Even if Plaintiffs had evidence that Pharmacy Defendants breached a duty to identify suspicious orders, they have no evidence that any breach of this duty caused their alleged injuries. Plaintiffs must identify evidence tracing their injuries to actual diversion from suspicious orders shipped by Pharmacy Defendants. They have not even attempted to do so.

Plaintiffs have failed to provide evidence that the alleged wrongdoing by Pharmacy Defendants caused them any injury. This Court should grant summary judgment in favor of the Pharmacy Defendants.

Dated: June 28, 2019

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